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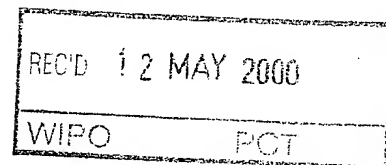
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# Kongeriget Danmark

Patent application No.: PA 1999 00463  
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Applicant: Coloplast A/S  
Holtedam 1  
DK-3050 Humlebæk

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28 April 2000

  
Jon Finsen  
Head of division

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**TITLE**

A pressure relieving dressing

**FIELD OF THE INVENTION**

The present invention relates to a pressure relieving dressing used for prophylaxis or treatment of ulcers.

**BACKGROUND OF THE INVENTION**

Many people, especially diabetics, who suffers from long term complications such as ischaemia and neuropathy or patients confined to their bed are known to develop ulcers on foot, hip or sacrum. Foot ulcers are usually located on the plantar or on the side or dorsum of the foot. Foot ulcers are induced by changes in bone structure, which can lead to protruding prominences and reduced thickness of the subcutaneous layer that ensures distribution of the pressure applied to the foot.

The development of foot ulcers are i.e. dependent on a combination of etiology and the induction of pressure. There are essentially two mechanical inducers for pressure sore development, the stress of permanent (static) pressure and the stress of short term (dynamic) pressure.

The permanent or static pressure is when exertion of pressure over a long period (hours typically) is leading to the risk of collapse of veins and arteries. The collapse of these blood vessels may lead to ischemia e.g. lack of oxygen and nutrition and a build up of waste materials. These events may eventually lead to development of ulcers. The tendency is the longer period of pressure induction, the lower pressure is critical and may cause damage.

Short term or dynamic pressure impact is in the form of repetitive mechanical stress. This occurs e.g. when walking, where typical a pre-stage to ulceration is callus build-up. This type of ulceration may be compared to benign sanguinous blister formation. Critical pressure level of this type of pressure impact is much

higher than in the case of a long time pressure load. However, the critical pressure level is still lower on e.g. diabetic feet compared to normal healthy feet.

Dressings designed to manage wound healing and exudate are well known in the art. However, they do not take into account the effects of the pressure stress.

- 5 From International Patent application No. WO 91/01706 A1 (Smith & Nephew) is known a polymeric foam absorbent dressing for exudate handling in wound healing. No pressure relief/distribution properties are mentioned. This dressing comprises a foam material all over the surface. Since this open cell foam is designed to allow transportation of exudate, it has inadequate strength towards
- 10 pressure, and will be compressed or collapse when worn on a foot.

WO 99/01166 A1 (Coloplast A/S) discloses a non-fibrous polysaccharide wound dressing capable of handling wound exudate by gelling properties. This material is very soft and gentle towards the ulcer. However, it has inadequate strength towards mechanical pressure and will collapse if pressure is applied.

- 15 Examples of pressure reducing/distributing/shock-lowering orthopaedic materials and products are also known:

In international Patent application No. WO 90/09746 A1 (Bernard, M.) is disclosed a composite inner sole for sports shoes, comprising a shock absorbing layer. No wound healing or exudate absorbing properties are mentioned.

- 20 US Patent No. 5 488 786 (Ratay, E.J.) discloses a highly resilient insole, designed to cover the whole sole of the shoe i.e. the whole plantar surface of the foot. No wound healing or exudate absorbing properties are mentioned.

Only few examples of a combination of the two said properties are known:

International Patent application No. WO 93/01777 A1 (Malloul, L.) discloses a dressing for sutured wounds. Said dressing has a foamed shock-absorbing element or cushion layer on both sides of the wound, protecting the wound from impact or pressure, and an area spaced apart from the wound with a pad right  
5 over the wound. The dressing only copes with dynamic pressure in the form of sudden impacts, and is silent with respect to static pressure.

European Patent No. EP 0 164 319 (Coloplast A/S) discloses a wound dressing of the hydrocolloid type with a pressure relief system of foam. The pressure is distributed through the foam in order to relieve the pressure on the ulcer. The  
10 dressing offers a possibility to adapt a specific relief area corresponding to the size of the ulcer, rendering it possible to transfer the pressure from the wound site to the surrounding healthy tissue. The pressure relief is described as having static pressure relieving properties, not dynamic pressure/shock relieving properties.

Until now a dressing being capable of both handling wound exudate and at the  
15 same time relieving both static and dynamic pressure has not been disclosed.

It has now surprisingly been found that the above mentioned problem can be overcome by combining a shock-absorbing material with a moisture-absorbing material rendering it is possible to obtain an effective and durable dressing suitable for both wound healing and prophylaxis of pressure ulcers.

## 20 **BRIEF DESCRIPTION OF THE INVENTION**

The present invention relates to a pressure relieving dressing comprising an absorbing element and a pressure distributing element.

## **BRIEF DESCRIPTION OF THE DRAWINGS**

The invention is explained more in detail with reference to the drawings in which:

25 Figure 1 shows a top view of an embodiment of the invention.

Figure 2 shows a cross-section of an embodiment of the invention.

Figure 3 shows a cross-section of another embodiment of the invention.

Figure 4 shows a further embodiment of the invention seen from above.

Figure 5 shows a cross-section of the embodiment of Figure 4.

Figure 6 shows a cross-section of yet another embodiment of the invention.

Figure 7 shows a cross-section of a still further embodiment of the invention.

## 5 DETAILED DESCRIPTION OF THE INVENTION

The invention relates to a pressure relieving dressing comprising an absorbing element and a pressure distributing element, which dressing is characterised in that the absorbent element constitutes a part of a proximal skin contacting surface, said absorbing element being encircled by the pressure distributing  
 10 element constituting the remaining part of the surface of the dressing to be in contact with the skin.

In order to prevent the development of ulcers and/or enhance the healing of ulcers a combination of an absorbing element and a pressure distributing and pressure shock-absorbing element has been shown to be advantageous. The  
 15 absorbing element is able to handle exudates from a wound and provide the optimal environment for wound healing, while the pressure distributing element will work as a shock absorber and a pressure distributing element and diminish further damage to the wound area.

The dressing according to the present invention reduces the impacts from  
 20 pressure shocks to the selected body part, and offers pressure distributing properties of susceptible areas. These properties are important both in the prophylactic phase as well as in the treatment of an ulcer. The absorbing element of the dressing of the invention is preferably more compressible than the pressure distributing element covering the area next to the treated areas and in that way  
 25 reducing the direct pressure on the wound.

The combination of an absorbing element combined with an pressure distributing element ensures that no changes in properties of the dressing due to long term pressure is observed. The dressing of the invention can be in the form of a very

flexible, thin device of a size rendering it suitable for wearing in shoes without discomfort.

In one embodiment of the invention the dressing may be substantially planar with circular or elliptical shape for use on e.g. heels.

- 5 In another embodiment of the invention the dressing may be in the form of a three-dimensional structure e.g. for use on toes.

The pressure distributing element is preferably an elastomer.

- The pressure distributing element may comprise synthetic polymers such as silicones, polyurethanes, elastomeric copolymers or hydrophobic foams with  
10 designed properties or it may be a natural polymer such as natural rubbers.

The elastomer has great ability of distributing both the static pressure and the sudden impacts, and at the same time it is durable and does not collapse during use, but conserves its elasticity and shape.

- In a preferred embodiment of the invention a water permeable elastomer is used,  
15 enabling water vapour transport through the dressing.

The product may be used both as an ulcer prophylaxis and as a wound dressing for all kinds of pressure ulcers, such as foot ulcers, leg ulcers, hip ulcers and sacrum ulcers.

- The absorbent element may comprise a hydrophilic foam, such as polyurethane,  
20 silicone, styrene-butadiene, styrene-isoprene or a surface coated polyethylene, or a water soluble or gelling biopolymers such as polysaccharides, e.g. alginates, polyvinyl-pyrrolidone gels or hydrocolloids.



Preferably the absorbent element is more compressible than the pressure distributing element.

The absorbent element may be located as discrete or connected zones in the pressure distributing element, either penetrating the pressure distributing element  
5 from top side to the skin-contacting side of the element or only going partly through the dressing, with the open end towards the skin.

The absorbent element is preferably in the form of a pattern of interconnected zones.

The zones of the absorbent element may be of any shape, e.g. in the form of  
10 dots, lines, squares or concentric circles.

In an embodiment of the invention the absorbent element may comprise more than one absorber, e.g. a foam part in the portion in contact with the skin, and on top of the foam a super absorber part being capable of soaking the moisture from the foam and in this way remove excess moisture from the skin-contacting part.

15 The device can be wholly or partly covered with an adhesive on the skin-facing surface to fix the device to the wearers body-part, e.g. the heel. Alternatively, the adhesive can be located on the non-skin facing side, and in this way attach the device to the innersole of the wearers shoe.

In one embodiment the pressure distributing element has adhesive properties

20 The device may be covered on the non-skin-contacting surface with a top layer, e.g. a foam, a non-woven, or a film, such as a polyurethane film. The layer will enhance the strength of the dressing as well as it may serve as a barrier for the wound exudate.

In one embodiment of the invention the top layer extends beyond the edge of the pressure distributing element defining a flange around the dressing. The flange may optionally be covered with an adhesive.

A protective cover or release liner may for instance be siliconised paper. It does  
5 not need to have the same contour as the dressing, e.g. a number of dressings may be attached to a larger sheet of protective cover. The protective cover is not present during the use of the dressing of the invention and is therefore not an essential part of the invention.

Furthermore, the dressing of the invention may comprise a "non touch" grip  
10 known per se for applying the dressing to the skin without touching the adhesive layer. Such a non-touch grip is not present after application of the dressing.

The dressing according to the invention may comprise wound healing associated indicator(s) such as indicators of pH, partial pressure of O<sub>2</sub>, temperature, radical mechanisms or biotechnological assays, e.g. indicating formation of collagen.

15 It is also advantageous that a dressing according to the invention comprises wound healing associated indicator(s), cushions or similar device for treatment or prophylaxis of formation of wounds and/or skin abnormalities.

This opens for a combined medical treatment of the wound and an easy and sterile application of the active ingredients, e.g. by incorporating active ingredi-  
20 ents such as a cytokine such as growth hormone or a polypeptide growth factor giving rise to the incorporation of such active substances in a form being apt to local application in a wound in which the medicament may exercise its effect on the wound, other medicaments such as bacteriostatic or bactericidal compounds, e.g. iodine, iodopovidone complexes, chloramine, chlorhexidine, silver salts  
25 such as sulphadiazine, silver nitrate, silver acetate, silver lactate, silver sulphate, silver-sodium-thiosulphate or silver chloride, zinc or salts thereof, metronidazol, sulpha drugs, and penicillins, tissue-healing enhancing agents, e.g. RGD

tripeptides and the like, proteins, amino acids such as taurine, vitamins such as ascorbic acid, enzymes for cleansing of wounds, e.g. pepsin, trypsin and the like, proteinase inhibitors or metalloproteinase inhibitors such as Illostat or ethylene diamine tetraacetic acid, cytotoxic agents and proliferation inhibitors for use in for example surgical insertion of the product in cancer tissue and/or other therapeutic agents which optionally may be used for topical application, pain relieving agents such as lidocaine or chinchocaine, emollients, retinoids or agents having a cooling effect which is also considered an aspect of the invention.

#### DETAILED DESCRIPTION OF THE DRAWINGS

10 A preferred embodiment of the invention is shown in Figure 1. In this embodiment, a zone of absorbing material (1) surrounded by a pressure distributing material (2).

In Figure 2 is shown a cross-section of the same embodiment of the invention as in Figure 1, with a zone of absorbent material (1) and a pressure distributing  
15 element (2). The edges of the dressing are bevelled or rounded to enhance the comfort of the dressing for the user. The edges may also be contoured so as to have a stepwise reduction of the thickness leaving a thinner flange part at the edge.

In Figure 3 is shown another embodiment of the invention in which the surface of  
20 the dressing not contacted with the skin is covered by a top layer (3). The top layer (3) may enhance the mechanical strength of the dressing.

Figure 4 shows another embodiment of the invention seen from above. The absorbent element (1) is distributed as discrete zones in the pressure distributing element (2).

25 In Figure 5 is shown a cross-section of the same embodiment of the invention with one absorbing element (1) at the skin-contacting surface, and on top of the this absorbing element is a super absorber (4).

In Figure 6 is shown another embodiment of the invention in which the edges are not bevelled, with a top layer (3) on one side and a layer of a an adhesive (5) on the skin-facing side.

Figure 7 is showing an embodiment of the invention in which the top layer (3) is  
5 elongated to extend beyond the pressure distributing element (2). On the elongated part of the layer (6) an adhesive (7) is applied, essentially making the concept an island dressing, with an adhesive flange and a non-adhesive centre part.

**CLAIMS**

1. A pressure relieving dressing comprising an absorbing element and a pressure distributing element, characterised in that the absorbent element constitutes a part of a proximal skin contacting surface, said absorbing element being encircled  
5 by the pressure distributing element constituting the remaining part of the surface of the dressing to be in contact with the skin.
2. A dressing according to claim 1, characterised in that the pressure distributing element is an elastomer.
3. A dressing according to claim 2, characterised in that the elastomer comprises  
10 a synthetic polymers such as silicones, polyurethanes, elastomeric copolymers or hydrophobic foams with designed properties or is a natural polymer such as natural rubber.
4. A dressing according to any of claims 1-3, characterised in that the absorbent  
15 element comprises a hydrophilic foam, such as polyurethane, silicone, styrene-butadiene, styrene-isoprene or a surface coated polyethylene, or a water soluble or gelling biopolymers such as polysaccharides, e.g. alginates, polyvinyl-pyrrolidone gels or hydrocolloids.
5. A dressing according to any of claims 1-4, characterised in that one of the  
20 surfaces of the dressing is partly or wholly covered with an adhesive or the pressure distributing element has adhesive properties.
6. A dressing according to any of claims 1-5, characterised in that the surface opposite the skin-contacting surface of the dressing is covered by a layer.
7. A dressing according to any of claims 1-6, characterised in that the absorbent element extends through the pressure distributing element.

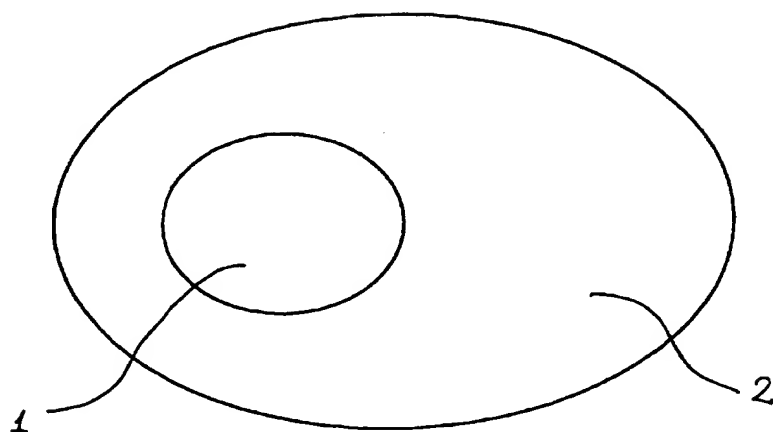
8. A dressing according to any of claims 1-6, characterised in that the absorbent element extend partly through the pressure distributing element.
9. A dressing according to any of claims 1-8, characterised in that the absorbent elements are in the form of multiple discrete zones in the pressure distributing  
5 element.
10. A dressing according to any of claims 1-9, characterised in that the absorbent element comprises a pharmaceutical or antimicrobial agent.

## ABSTRACT

### A pressure relieving dressing

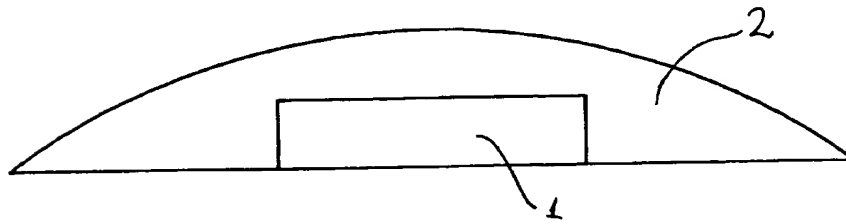
A pressure relieving dressing comprising an absorbing element and a pressure distributing element, in which the absorbent element constitutes a part of a proximal skin contacting surface, said absorbing element being encircled by the  
5 pressure distributing element constituting the remaining part of the surface of the dressing to be in contact with the skin rendering it possible to obtain an effective and durable dressing suitable for both wound healing and prophylaxis of pressure ulcers.

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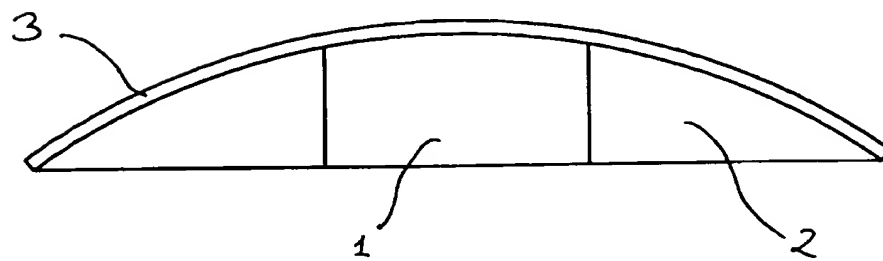


*Fig. 1*



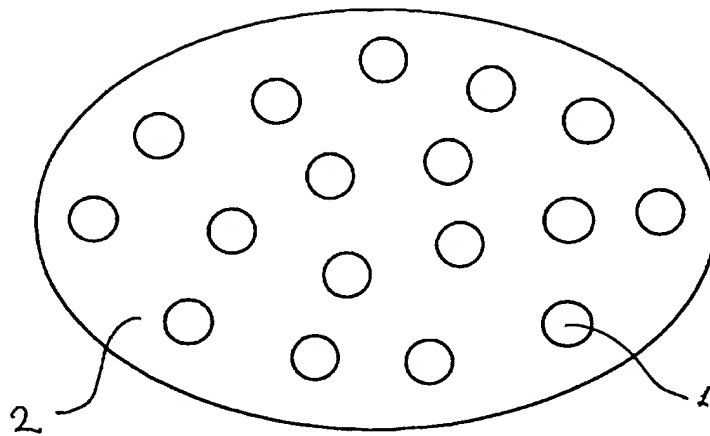


*Fig. 2*

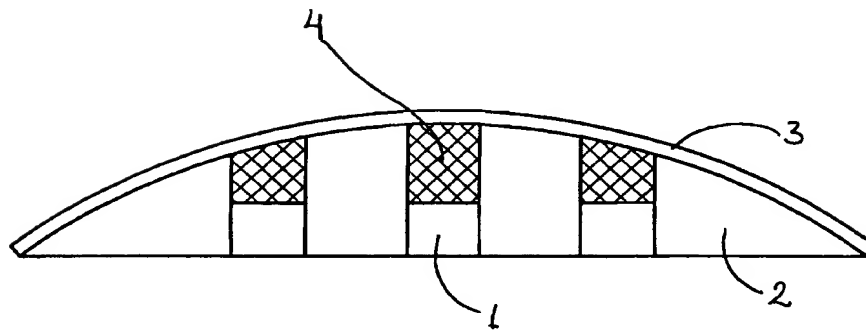


*Fig. 3*

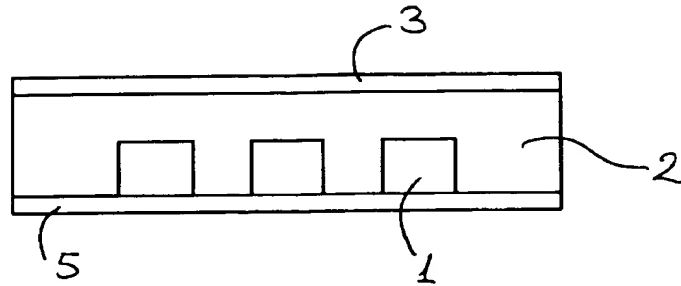
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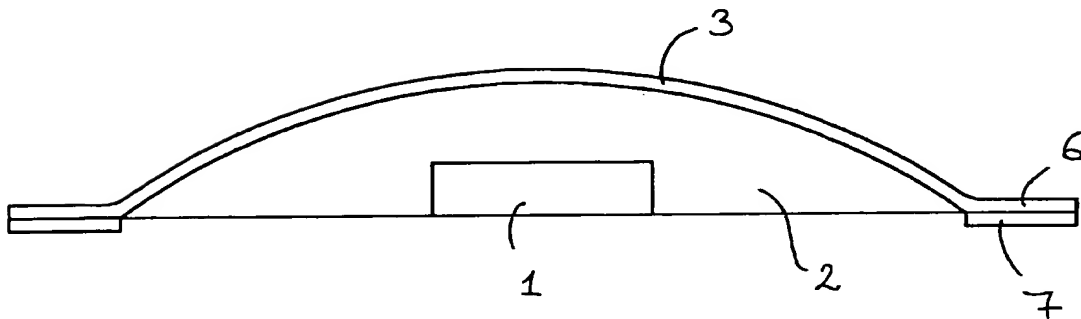
*Fig. 4*



*Fig. 5*



*Fig. 6*



*Fig. 7*

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